5. 510(k) SUMMARY

DEC 19 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K132086.

Submitter's Identification:

ACON Laboratories, Inc.

10125 Mesa Rim Road

San Diego, California 92121

Tel.: 858-875-8019
Fax: 858-875-8099

Date Prepared: August 21, 2013

Contact Person:

Qiyi Xie
Senior Staff, Clinical & Regulatory Affairs

Proprietary Name of the Device:

On Call® Express Blood Glucose Monitoring System

Common Name:

Glucose Test System

Classification Name:

Class II §862.1345 Glucose Test System

Predicate Device:

On Call® Vivid Blood Glucose Monitoring System
ACON Laboratories, Inc., located at 10125 Mesa Rim Road, CA 92121, USA.
510(k) Number: K112653

Device Name: On Call® Express Blood Glucose Monitoring System

Proprietary Name	Classification	Product Code	Description	Common Name
On Call® Express Blood Glucose Monitoring System	862.1345 Class II	75 NBW	System, Test, Blood Glucose, Prescription	Glucose Test System
On Call® Express Blood Glucose Meter and On Call® Express Blood Glucose Test Strips	862.1345 Class II	75 LFR	Glucose Monitor	Glucose Meter & Test Strips
On Call® Express Glucose Control Solution	862.1660 Class I	75 JJX	Single Analyte Control	Control Solution

Description:

The On Call® Express Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in capillary whole blood sampled from the fingertip, palm and forearm. The glucose measurement is achieved by using the amperometric detection method.

The test strip has a reagent system including glucose oxidase and a mediator that reacts with glucose in the whole blood sample to produce an electrical current. This current is measured by the meter, and after calculation by the meter, the blood glucose concentration reading is displayed on the meter display, calibrated to a plasma reference.

Intended Use:

The On Call® Express Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, forearm and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Alternative site testing should be done only during steady-state times (when blood glucose level is not changing rapidly). The On Call® Express Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is for in vitro diagnostic use only.

The On Call® Express Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, nor intended for use on neonates.

The On Call® Express Blood Glucose Test Strips are used with the On Call® Express Blood Glucose Meter in the quantitative measurement of glucose in capillary blood from the fingertips, forearm and palm.

The On Call® Express Blood Glucose Control Solution is for use with the On Call® Express Blood Glucose Meter and Strips as a quality control check to verify the accuracy of blood glucose test results.

Technological Characteristics:

Specification of Blood Glucose Meter:

Feature	Specification
Measurement Range	20 to 600 mg/dL (1.1-33.3 mmol/L)
Result Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Minimum Sample Size	0.4 µL
Test Time	4 seconds
Power Source	One (1) CR 2032 3.0V coin cell battery
Battery Life	1,000 tests for glucose testing (not considering data transfer)
Glucose Units of Measure	The meter is preset to mg/dL when sold in the United States.
Memory	Up to 300 records with time and date
Automatic Shutoff	2 minutes after last action
Meter Size	3.46" x 1.93" x 0.65"
Display Size	1.38" x 1.26"
Weight	Approximately 50 g (with battery installed)
Operating Temperature	41-113°F (5-45°C)
Operating Relative Humidity	10-90% (non-condensing)
Hematocrit Range	30-55%
Data Port	9600 baud, 8 data bits, 1 stop bit, no parity

Comparison to Predicate Devices:

The On Call® Express Blood Glucose Monitoring System is substantially equivalent to The On Call® Vivid Blood Glucose Monitoring System, K112653.

Features	On Call® Vivid Blood Glucose Monitoring System (K112653)	On Call® Express Blood Glucose Monitoring System
	Similarities	
Result Calibration	Plasma-equivalent	Same
Sample Type	Fresh capillary whole blood	Same
Assay Method	Glucose oxidase	Same
Glucose Units of Measure	mg/dL	Same
Operating Relative Humidity	10–90%	Same
Data Port	One Serial data port	Same
Measurement Range	20 to 600 mg/dL (1.1-33.3 mmol/L)	Same
Automatic Shutoff	Two minutes after last user action	Same
Battery Life	Minimum of **1,000** measurements (without considering data transfer and test reminder alarms)	Same
Coding	Auto Coding by meter automatic recognition of the intended coding after strip insertion	Same
	Differences	
Hematocrit Range	25–70%	30–55%
Operating Temperature	10–45°C (50–113°F)	41-113°F (5-45°C)
Test Time	5 seconds	4 seconds
Minimum Sample Size	0.8 µL	0.4 uL
Meter Memory	Up to 500 records with time and date	Up to 300 records with time and date
Power Source	Two (2) CR 2032 3.0 V coin cell batteries	One (1) CR 2032 3.0V coin cell battery
Meter Size	3.53" x 2.28" x 0.85" (89.6mm x 58mm x 21.7mm)	3.46" x 1.93" x 0.65"
Meter Weight	Approx. 60 g (with battery installed)	Approx. 50 g (with battery installed)
Meter Display Backlight	Yes	No
Meter Strip Port Light	Yes	No

Discussions of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Guidance documents included the "FDA Guidance for Industry In Vitro Diagnostic Glucose Test System" and "FDA Guidance for Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems" as well as "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Compliance to applicable voluntary standards includes EN ISO 15197:2003 "In vitro diagnostic test systems – Requirements for in vitro whole blood glucose monitoring systems intended for use by patients for self-testing in management of diabetes mellitus."

Laboratory Testing:

The performance characteristics of the On Call® Express Blood Glucose Monitoring System were evaluated by performing the following safety and reliability testing per ISO 15197:2003, Section 6: repeatability precision, intermediate precision, accuracy evaluation, user performance, linearity, interfering agents, , altitude effect, system traceability, validation of calibration control materials, hematocrit effect, temperature effect evaluation – blood & control solution, low battery effect evaluation, , sample volume, temperature effect evaluation (blood and control solution), humidity effect, simulated shipping studies – test strip & control solution, accelerated Use Life (control & strip), 65° Accelerated Stability (Strip & Control), packaging, vibration, drop tests, temperature exposure, and humidity exposure, control value assignment, virucidal efficacy validation, meter cleaning and disinfection, meter testing, software validation testing, electromagnetic compatibility and electrical safety testing (per EN/IEC 61010-1 & 61010-2-101) as part of meter and strip validation testing.

Discussion of Clinical Tests Performed:

Clinical studies were conducted with lay persons and trained laboratory technicians using the On Call® Express Blood Glucose Monitoring System. The study data were presented evaluating the system accuracy of the On Call® Express Blood Glucose Monitoring System compared to the YSI Model 2300 STAT PLUS (K913806) per the ACON Clinical Study Protocol for the Blood Glucose Monitoring System. Study results indicate that nonprofessional, inexperienced lay persons were able to obtain comparable blood glucose readings when using the On Call® Express Blood Glucose Monitoring System as compared to the results obtained by the trained technicians. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User's Manual and the overall performance of the On Call® Express Blood Glucose Monitoring System.

Conclusion:

The laboratory testing and clinical study results demonstrate that the On Call® Express Blood Glucose Monitoring System is safe, effective and easy-to-use. It also demonstrates that the On

Call® Express Blood Glucose Monitoring System meets the accuracy requirements per EN ISO 15197:2003 and as such is substantially equivalent to the On Call® Vivid Blood Glucose Monitoring System, currently sold on the U.S. market (K112653).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2013

ACON LABORATORIES, INC.
QIYI XIE, M.D., MPH
SR. STAFF (RA/CA)
10125 MESA RIM ROAD
SAN DIEGO CA 92121

Re: K132086
Trade/Device Name: On Call Express Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: November 05, 2013
Received: November 06, 2013

Dear Dr. Xie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k132086

Device Name
On Call® Express Blood Glucose Monitoring System

Indications for Use *(Describe)*

The On Call® Express Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, forearm and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Alternative site testing should be done only during steady-state times (when blood glucose level is not changing rapidly).

The On Call® Express Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is for in vitro diagnostic use only.

The On Call® Express Blood Glucose Monitoring System in not intended for the diagnosis of or screening for diabetes, nor *intended* for use on neonates. The On Call® Express Blood Glucose Test Strips are used with the On Call Express Blood Glucose Meter in the quantitative measurement of glucose in capillary blood from the fingertips, forearm and palm.

The On Call® Express Blood Glucose Control Solutions are for use with the On Call® Express Blood Glucose Meter and On Call® Express Blood Glucose Test Strips to check that the meter and test strips are working together properly and the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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